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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/585,058 | 06/30/2006 | Yair Saar | 0146.00002 | 5559 |
| 7590 | 01/02/2009 | | EXAMINER | |
| Kenneth I Kohn Kohn & Associates 30500 Northwestern Highway Suite 410 Farmington Hills, MI 48334 | | | MOSHER, MARY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/585,058 | SAAR, YAIR | |
| | Examiner | Art Unit | |
| | Mary E. Mosher | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10/3/08, 10/14/08.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-5, 7-9, 12-33 and 35-38 is/are pending in the application.

4a) Of the above claim(s) 12-28 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2-4, 7-9, 29-33 and 35-38 is/are rejected.

7) Claim(s) 5 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

In response to the amendments filed 10/3/08 and 10/14/08, the rejections of record are withdrawn.

Claim Rejections - 35 USC § 112

Claims 29, 38, and dependent claims 8, 9, 30-33, 35, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 29 and 38 are indefinite because they lack antecedent for "said vaccine". In the interest of compact prosecution, claims 29 and 38 have been treated as if they depended from claim 37. However, this treatment does not relieve applicant of the burden of response to this rejection.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a

required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation “herpes viruses”, and the claim also recites “especially Marek’s disease viruses” which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 38, 2, 3, 8, 29, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Cabasso et al. Cabasso teaches smallpox vaccines made by freeze-drying vaccinia-infected calf skin pulp or chick chorioallantoic membranes, in the presence of a stabilizing buffer carrier or excipient. Although the reference does not explicitly state that the vaccinia virions are viable, or that they are contained within dried cells having membranes, or that they are double stranded DNA virions, these are all inherent characteristics that would necessarily be present because of the nature of the virus and the nature of the production process. Therefore, the reference explicitly or inherently meets every limitation of these claims.

Claims 37, 38, 1-4, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by DD 235775. Please note, the disclosure in the patent is only one page long, and a machine translation and a copy of the Derwent abstract are appended to the copy of the

patent provided. The patent discloses a vaccine against Marek's disease virus (MDV), comprising lyophilized duck embryo cells infected with herpesvirus of turkeys (HVT). The working example includes a final suspension medium with 10% bovine serum, which medium constitutes a carrier or cryoprotectant or excipient. Therefore the reference meets each and every limitation of these claims.

Claim Rejections - 35 USC § 103

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cabasso et al. As discussed above, Cabasso discloses vaccines per se; packaging in vials is also disclosed. Claim 7 differs from Cabasso only in that Cabasso does not disclose, as an article of manufacture, instructions for use of the vaccines to be supplied together with the vials. However, providing written instructions for use of a vaccine was conventional at the time of the invention. Therefore, the invention as a whole is *prima facie* obvious, absent unexpected results.

Claims 7, 29-32, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over DD 235775. As discussed above, the patent discloses a vaccine comprising dried infected cells containing HVT. The patent differs from these claims in that it does not disclose details of the method of administering the vaccine to subjects, or disclose packaging with instructions. However, since the vaccine is explicitly suggested for use in chickens, it would have been a matter of routine to determine conditions for administration, and to include instructions for use with the packaged vaccine. Therefore, the invention as a whole is *prima facie* obvious, absent unexpected results.

Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The DD patent does not teach or suggest substitution of Marek's disease virus for the HVT in the lyophilized infected cells, and the bulk of the prior art teaches frozen cell-associated MDV in vaccines, not dried cell-associated MDV in vaccines.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is 571-272-

0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

12/30/08